

# Exhibit G



# Current Trends in DEA Compliance

## National Association Chain Drug Stores

August 24, 2015



The United States Department of Justice  
**Drug Enforcement Administration**

Ruth A. Carter, Chief  
Liaison and Policy Section  
Office of Diversion Control







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# ***What People Are Abusing***

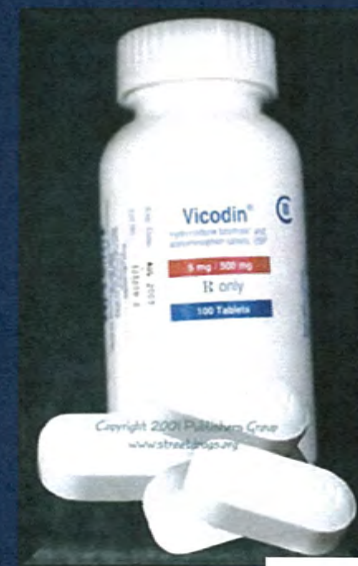
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# Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)
- Similarities:
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects
- Brand Names: Vicodin<sup>®</sup>, Lortab<sup>®</sup>, Lorcet<sup>®</sup>
- Currently, combination products are Schedule III
- **October 6, 2014 moved to SCHEDULE II**
- “Cocktail” or “Trinity”
  - Hydrocodone
  - Soma<sup>®</sup> / carisoprodol
  - Alprazolam / Xanax<sup>®</sup>
- Street prices: \$2 to \$10+ per tablet depending on strength & region







# ***Worldwide Hydrocodone Use***

- 67 Countries reported an estimated need requirement for hydrocodone to the International Narcotics Control Board
- 20 countries reported an estimated need of 1 kilogram or greater.
- 4 countries reported an estimated need between 500 grams and 999 grams
- 10 countries reported an estimated need between 100 grams and 499 grams
- 6 countries reported a need between 25 grams and 99 grams
- 27 countries reported a need of less than 25 grams

SOURCE: UN International Narcotics Control Board website. Estimated World Requirements of Narcotic Drugs in grams for 2014.  
<http://www.incb.org> . Accessed April 14, 2014

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Office of Diversion Control*





# ***Worldwide Hydrocodone Use***

- **Of the 20 Countries** that reported an estimated needs requirement for hydrocodone at one kilogram or more
- **8 countries** reported an estimated need of 1 kilogram to 5 kilograms
- **4 countries** reported an estimated need over 5 kilograms to 10 kilograms
- **8 countries** reported an estimated need over 10 kilograms

SOURCE: UN International Narcotics Control Board website. Estimated World Requirements of Narcotic Drugs in grams for 2014. <http://www.incb.org> . Accessed April 14, 2014

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## *Top 10 List*

➤ 10 Guatemala	10 kilograms
➤ 09 India	10 kilograms
➤ 08 Vietnam	20 kilograms
➤ 07 China	20 kilograms
➤ 06 Denmark	25.5 kilograms
➤ 05 Columbia	30 kilograms
➤ 04 Syrian Republic	50 kilograms
➤ 03 Canada	115.5 kilograms
➤ 02 United Kingdom	200 kilograms
➤ 01 United States	79,700 kilograms 99.3%

SOURCE: UN International Narcotics Control Board website. Estimated World Requirements of Narcotic Drugs in grams for 2014. <http://www.incb.org>. Accessed April 14, 2014

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# The Trinity

Hydrocodone



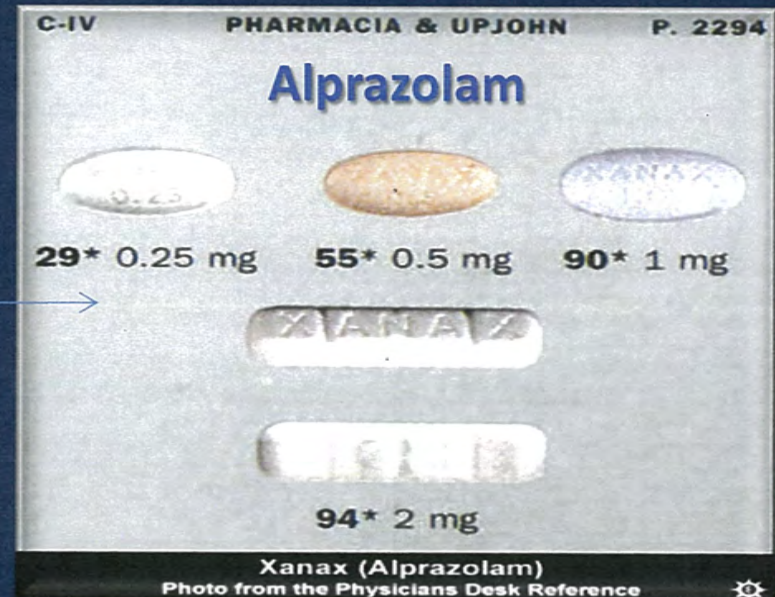
Opiate

Carisoprodol



C-IV as of 1/11/2012

Muscle Relaxant

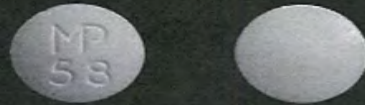


Benzodiazepine



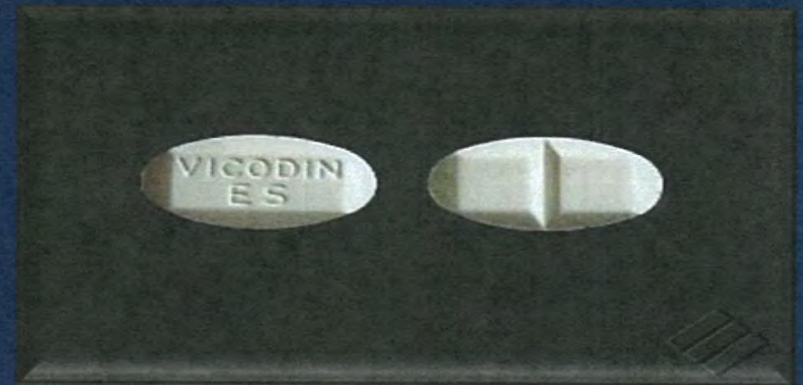


Carisoprodol



C-IV as of 1/11/2012

## Commonly Abused Controlled Substances



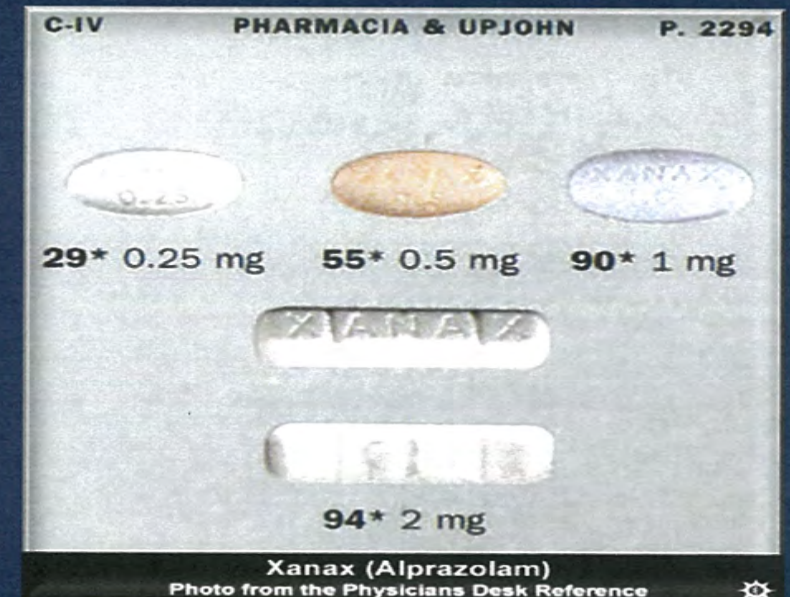
Hydrocodone



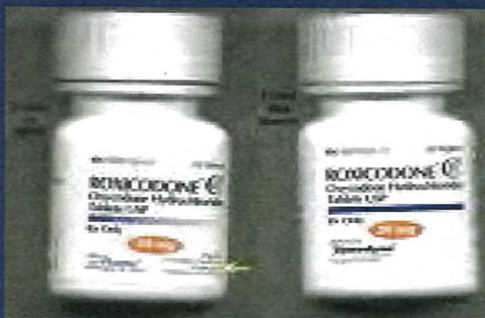
OxyContin 80mg



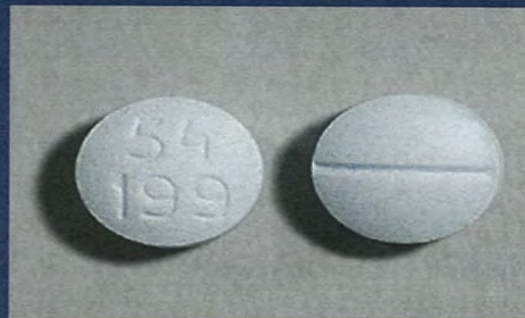
Oxymorphone



Alprazolam



Oxycodone 30 mg



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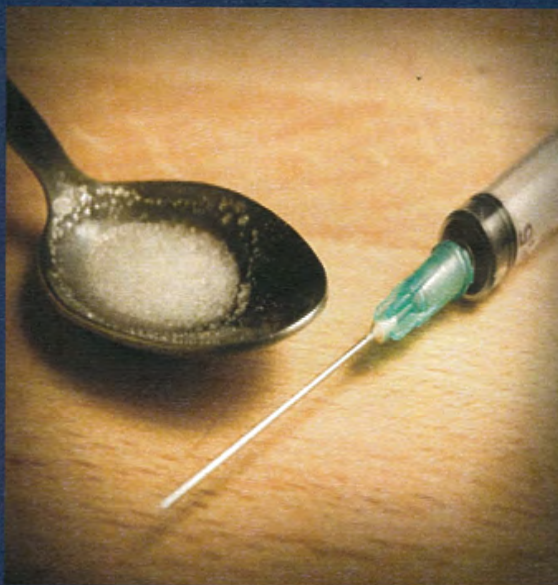
# Oxycodone

- OxyContin controlled release formulation of Schedule II oxycodone
  - The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
  - Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
  - 10, 15, 20, 30, 40, 60, 80mg available
- Effects:
  - Similar to morphine in effects and potential for abuse/dependence
  - Sold in “Cocktails” or the “Holy Trinity” (Oxycodone, Soma<sup>®</sup> / carisoprodol, Alprazolam / Xanax<sup>®</sup>)
- Street price: Approx. \$80 per 80mg tablet
- NOTE: New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.





## *Prescription Opiates vs. Heroin*



*U.S. Drug Enforcement Administration  
Office of Diversion Control*





# *The Circle of Addiction & The Next Generation*

Oxycodone  
Combinations

Percocet®

\$7-\$10/tab

Hydrocodone

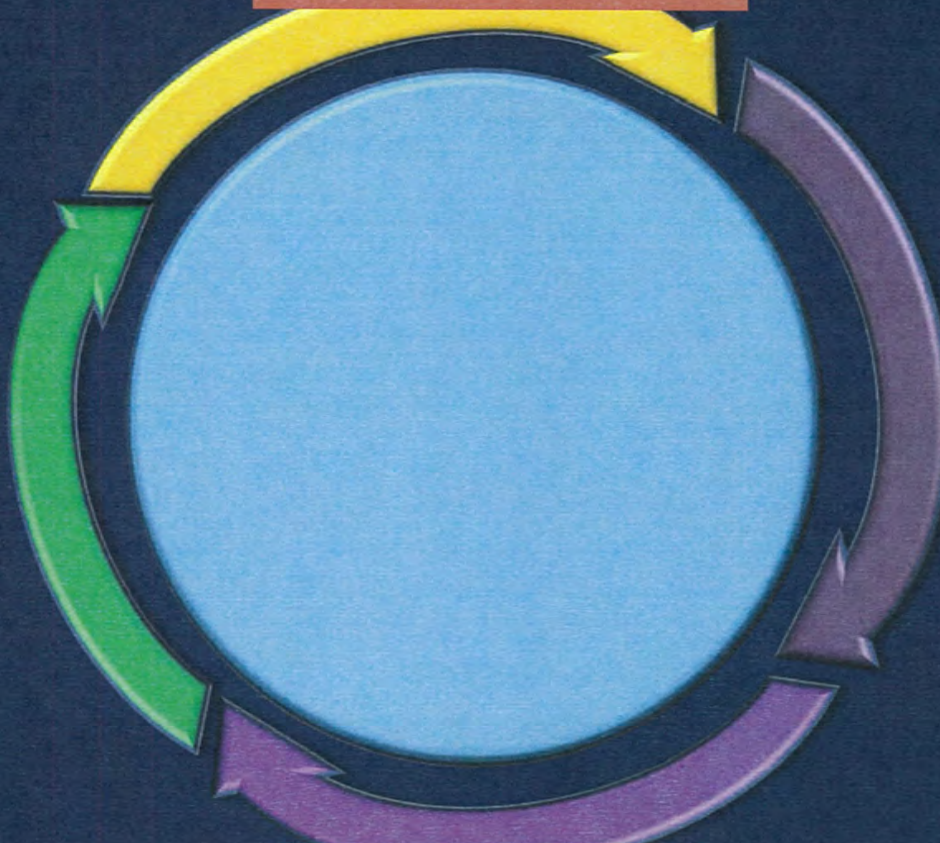
Lorcet®

\$5-\$7/tab

OxyContin®  
\$80/tab

Roxicodone®  
Oxycodone IR  
15mg, 30mg  
\$30-\$40/tab

Heroin  
\$15/bag







# Heroin: No Longer Confined to Urban Areas

**NOW OPEN**  
**DARCARS**  
See what it's like to love car buying  
**OF SILVER SPRING**  
Sales & Service  
12511 Prosperity Drive • Silver Spring, MD 20904  
**1-888-589-3065**  
www.DARCARSvolkswagen.com  
Call / Email Alex Pedram, General Sales Manager  
APedram@darcars.com

washingtonexaminer.com

**The Examiner**  
WASHINGTON  
WEDNESDAY, DECEMBER 5, 2012

**Ship's Hatch**  
Army, Navy,  
USAF, USMC & USCG  
Promotion/Retirement  
Gifts, Flag Cases,  
Presentation Checks  
703.413.6289  
www.ships Hatch.com  
Located in the Shops at Crystal City

**'Liaisons Dangereuses'**  
New approach to classic P. 19

**Playoff possibilities**  
Schedule favors Skins P. 35

**Cooling down**  
60° 34°  
DETAILS P. 4

**POLITICS**  
**Stalemate on 'cliff'**  
Sides stop talking;  
Obama's rate hikes  
may be flexible. P. 13

**LOCAL**  
**FBI analyst husted**

## Heroin use spikes in area suburbs Pill addicts risk deadly drug





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# ***The CSA: Checks and Balances***

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U.S. Drug Enforcement Administration  
Office of Diversion Control





# *Mission*

The mission of the Office of Diversion Control is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

*while ...*

ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs





# *Cutting off the Source of Supply*







# ***Closed System of Distribution***

1,599,457 (08/14/15)

**Practitioners:**

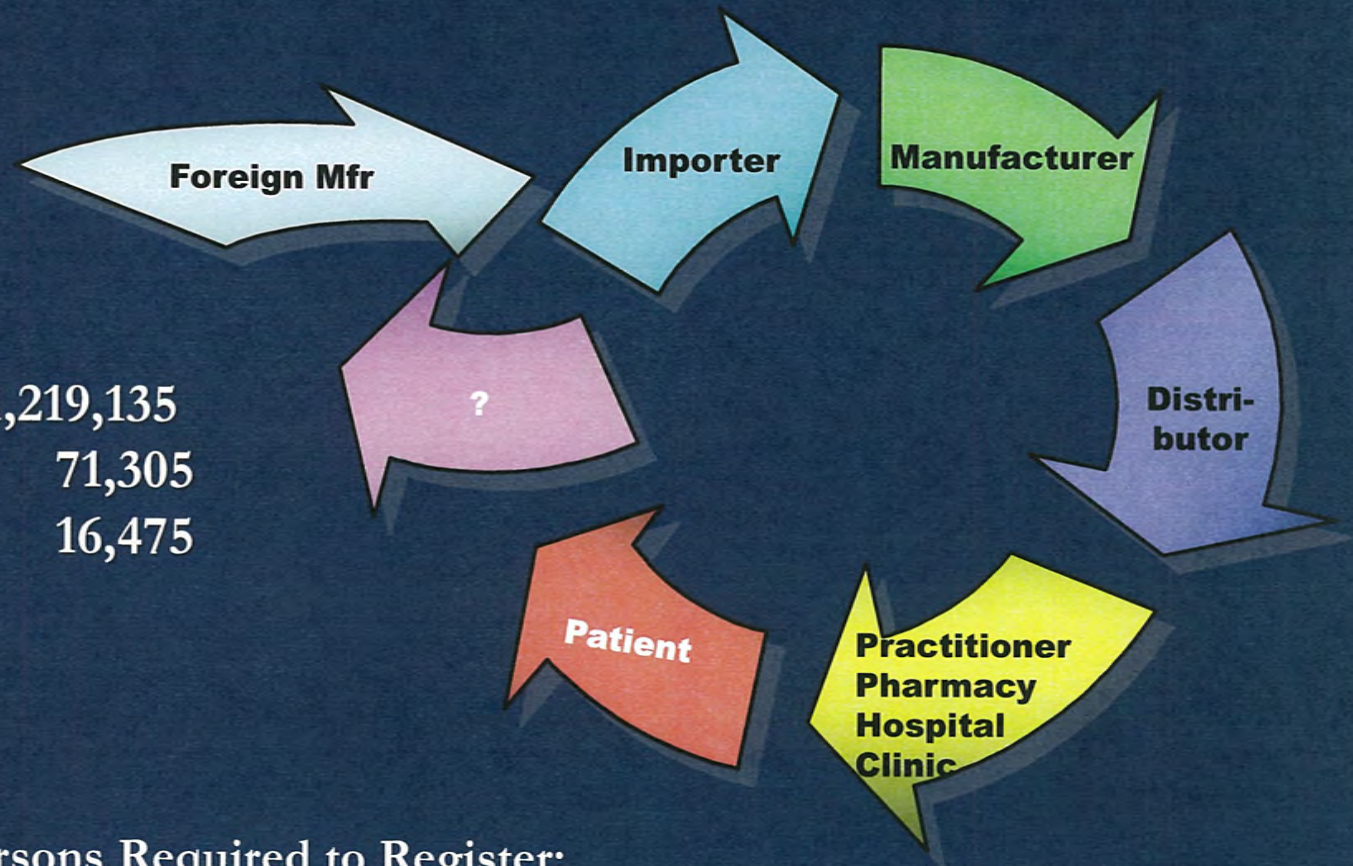
**Retail Pharmacies:**

**Hospital/Clinics:**

1,219,135

71,305

16,475



**Law: 21 USC 822 (a) (1) Persons Required to Register:**

“Every person who manufactures or distributes any Controlled Substance or List I Chemical or who proposes to engage in ..”

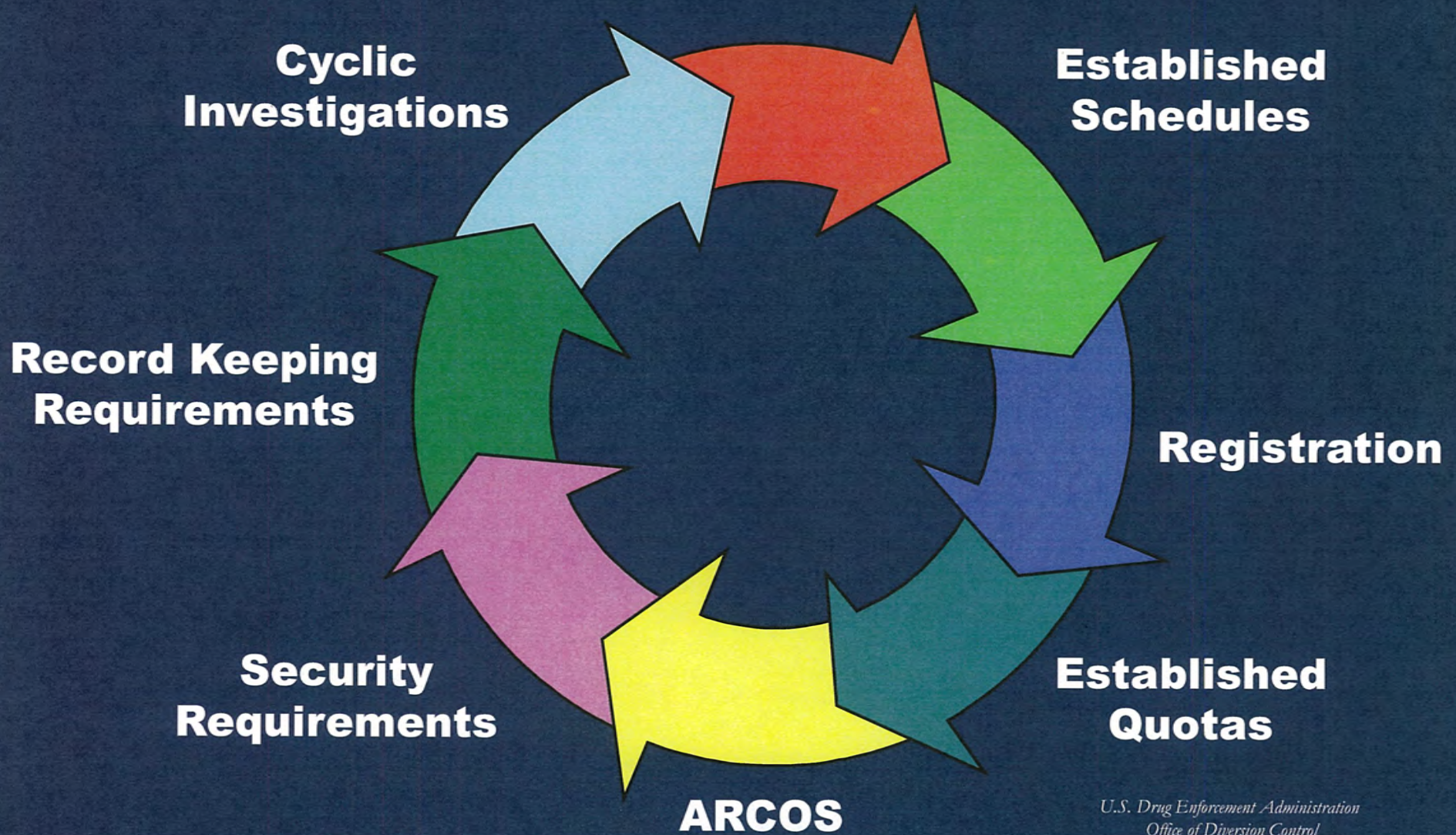
**Law: 21 USC 822 (a) (2) Persons Required to Register:**

“Every person who dispenses, or who proposes to dispense any controlled substance ...”





# ***Closed System of Distribution***







# ***Closed System of Distribution***

The DEA is responsible for:

- the **oversight** of the system
- the **integrity** of the system
- the **protection** of the public health and safety



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Office of Diversion Control*





# ***DEA Registrant Initiatives***

## **Distributor Initiative**

Educate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances

**August 1, 2005 – August 21, 2015:** Briefings to **85** firms with **280** registrations



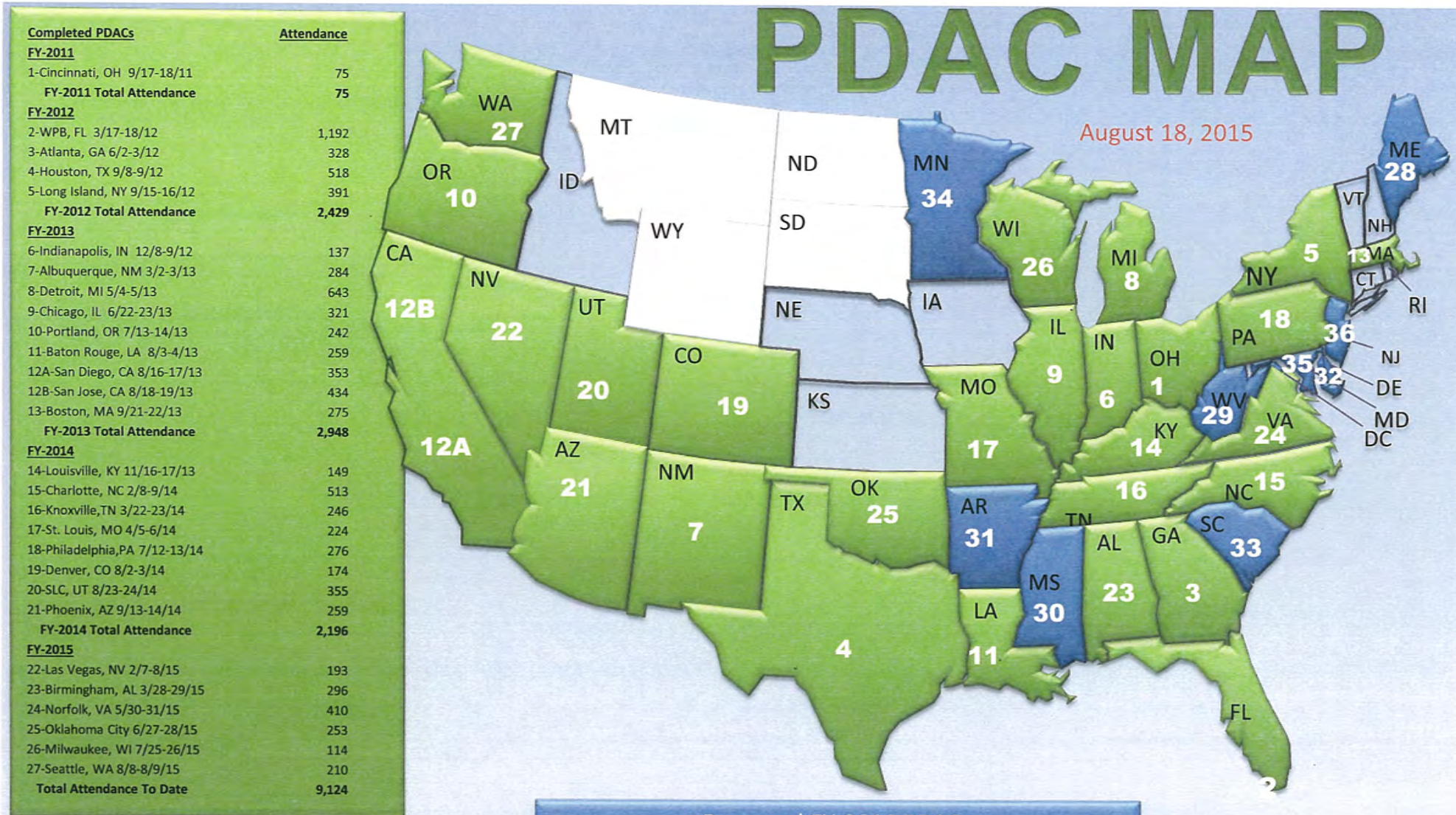


# ***DEA Registrant Initiatives***

## **Pharmacy Diversion Awareness Conference**



This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity





Approved FY 2015 PDACs  
 28-Portland, ME September 12-13, 2015

Proposed FY-2016 PDACs  
 29-Little Rock, Arkansas November 2015  
 30-Jackson, MS January 2016  
 31-Charleston, WV February 2016  
 32-Wilmington, Delaware March 2016  
 33-Charleston, South Carolina April 2016  
 34-Minneapolis/St. Paul, Minnesota July 2016  
 35-Towson, Maryland August 2016  
 36-New Brunswick, New Jersey September 2016

 Completed PDACs  
 Proposed PDACs





# ***DEA Registrant Initiatives***

## **"Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances"**

- Represents the medical, pharmacist, and supply chain spectrum highlighting the challenges and "red flag" warning signs related to prescribing and dispensing controlled substance prescriptions
- The goal was to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny
- NABP along with 10 national associations and 6 major pharmaceutical firms were the coalition of stakeholders of this document.





# ***DEA Registrant Initiatives***

- The Federation of State Medical Boards (FSMB) promotes excellence in medical practice, licensure, and regulation on behalf of 70 state medical and osteopathic Boards across the country in their protection of the public
- DEA and FSMB are currently working on developing strategies to work more effectively and jointly on indiscriminate prescriber investigations in order to facilitate the administrative process to take action against those that are a threat to the public health and welfare quickly, and at the same time not jeopardize a criminal investigation





# *Scheduled Investigations*

- Increase in the number of DEA registrants that are required to be investigated to ensure compliance with the Controlled Substances Act and its implementing regulations
- Increase in the frequency of the regulatory investigations
- Verification investigations of customers and suppliers





# *Effective Controls*

21 CFR § 1301.71(a)

*“All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”*





# *Effective Controls*

## 21 CFR § 1301.71(a)

In order to determine whether a registrant has provided **effective controls** against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for the **physical security controls** and **operating procedures** necessary to **prevent diversion**





# *Suspicious Orders*

21 CFR § 1301.74(b)

*Non-practitioners* of controlled substances

*“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”*



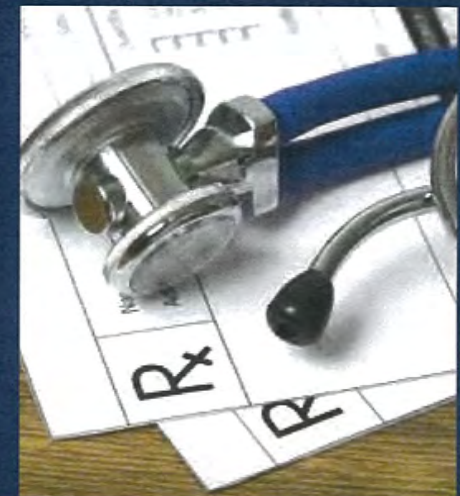
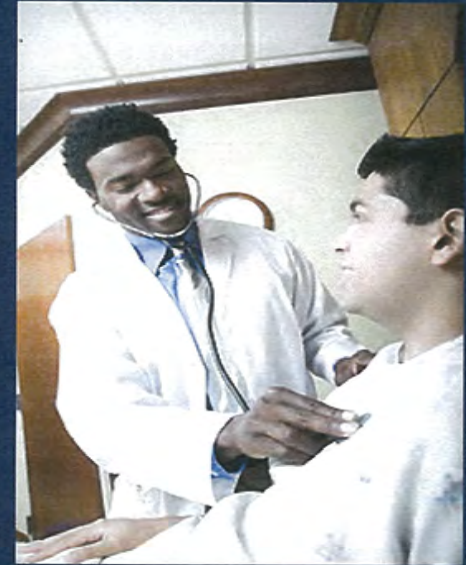


# Prescriptions

21 CFR § 1306.04(a)

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

*United States v Moore* 423 US 122 (1975)







# ***Checks and Balances Under the CSA***

## **Pharmacists – The Last Line of Defense**

***“The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”***

**(21 CFR § 1306.04(a))**

*U.S v. Hayes 595 F. 2d 258 (5<sup>th</sup> Cir 1979)*

*U.S. v. Leal 75 F. 3d 219 (6<sup>th</sup> Cir 1996)*

*U.S. v. Birbragher 603 F. 3d 478 (8<sup>th</sup> Cir 2010)*

*East Main Street Pharmacy 75 Fed. Reg. 66149 (Oct. 27, 2010)*





# ***Checks and Balances Under the CSA***

## **Pharmacists – The Last Line of Defense**

***“An order purporting to be a prescription issued not in the course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the act (21 USC 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” (21 CFR § 1306.04(a))***

*U.S v. Hayes 595 F. 2d 258 (5<sup>th</sup> Cir 1979)*

*U.S. v. Leal 75 F. 3d 219 (6<sup>th</sup> Cir 1996)*

*U.S. v. Birbragher 603 F. 3d 478 (8<sup>th</sup> Cir 2010)*

*East Main Street Pharmacy 75 Fed. Reg. 66149 (Oct. 27, 2010)*





# *The Last Line of Defense*



U.S. Drug Enforcement Administration  
Office of Diversion Control





# *Corresponding Responsibility*

21 CFR § 1306.04(a)

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.







## *Corresponding Responsibility*

- A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate
- Just because a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription!!!





# ***DEA Legal Resources***

## ➤ Administrative

Immediate Suspension Order (ISO)

Memorandum of Agreement (MOA)

Order to Show Cause (OTSC)

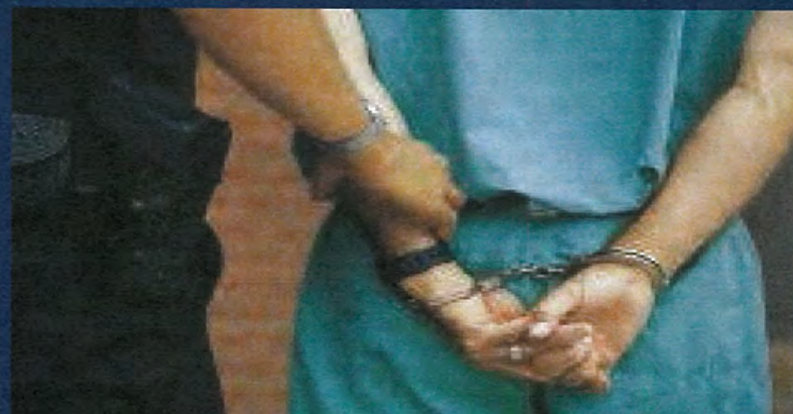
## ➤ Civil

Fines

## ➤ Criminal

Arrests

Criminal fines







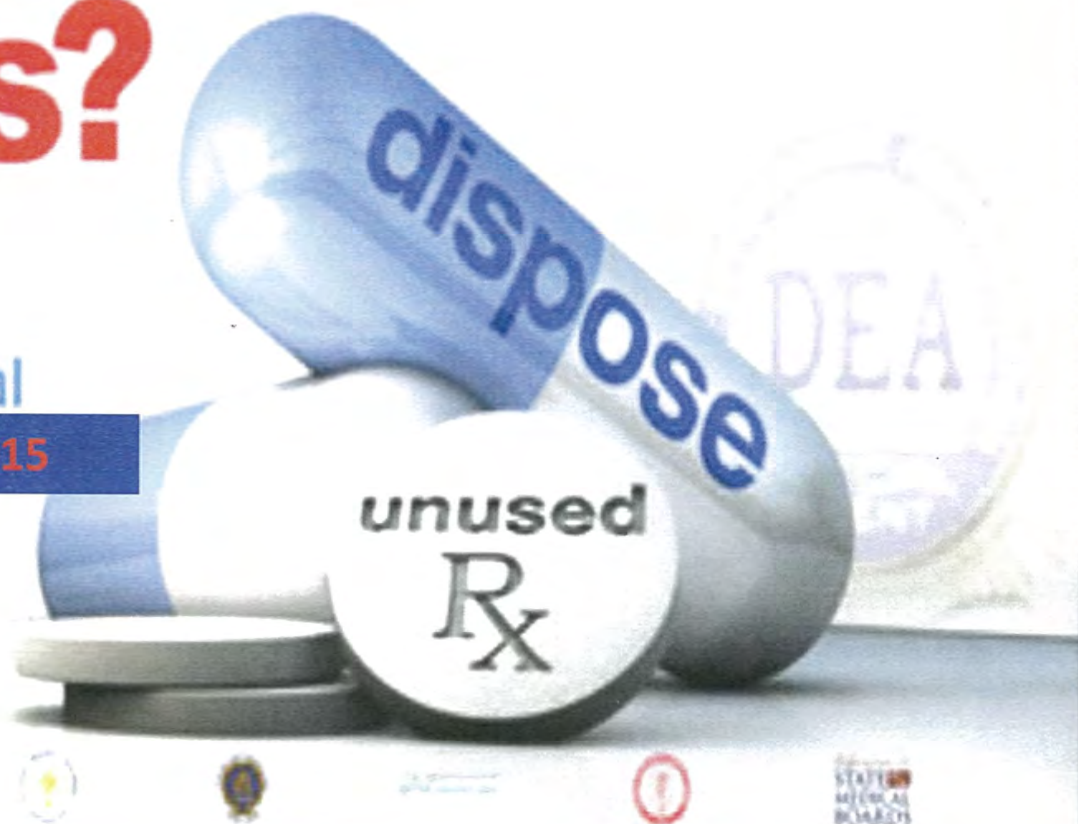
# *National Take Back Initiative*

## *September 26, 2015*

# Got Drugs?

Turn in your  
unused or expired  
medication for safe disposal  
Saturday **September 26, 2015**

Click here  
for a collection  
site near you.



10:00 AM – 2:00 PM

U.S. Drug Enforcement Administration  
Office of Diversion Control





# DEA Web-Based Resources

Office of Diversion Control  
[www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

U.S. Department of Justice Drug Enforcement Administration  
**Office of Diversion Control**

Home | About | Help | News | Contact

Registration  
 Reporting  
 Info & Legal Resources  
 Media Center | Home

**Got Drugs?**

**EMERGENCY Disaster Relief**

**ALERT US**

**Extortion SCAM**

**Regulations.gov**

**The police in Federal decision-making**

**Drug Mediation, Not Retaliation**

**Drug Diversion in America**

**Let's Make "MURDER"**

External links included in this website are not endorsed or approved by the U.S. Department of Justice. The U.S. Department of Justice is not responsible for the content of any external website.

**Report Illicit Pharmaceutical Activities**

**1-877-RX-ABUSE  
 1-877-792-2873**

**What's New**

**Let's Make "MURDER"**  
 Let's Make "MURDER" is a new initiative to help law enforcement agencies identify and prosecute drug traffickers. The initiative is a partnership between the DEA and the FBI. The initiative is a partnership between the DEA and the FBI. The initiative is a partnership between the DEA and the FBI.

**Registration Support**

**Registration Number Toll Free: 1-800-882-9539 (8:30 am-6:00 pm EST)**

Save time by applying for your registration online. Data will be entered through a secure connection to the CDWR online web application system.

**Minimum requirements:** Credit Card and a web browser that supports 128-bit encryption.

**Upcoming Meetings**

**Hurricane Sandy**

Messages from New Jersey and New York Area Registrants - As you know, Hurricane Sandy impacted the New Jersey and New York area particularly hard. States of the DEA's offices in these two states have also been impacted by the storm. If you are not able to submit your local DEA Fee, please provide the following information to the DEA's main toll-free number at 1-800-882-9539. Thank you for your patience.

**Quick Links**

[Home](#)  
[About](#)  
[Help](#)  
[News](#)  
[Contact](#)  
[Registration](#)  
[Reporting](#)  
[Info & Legal Resources](#)  
[Media Center](#)  
[The police in Federal decision-making](#)  
[Drug Mediation, Not Retaliation](#)  
[Drug Diversion in America](#)  
[Let's Make "MURDER"](#)

**FAQ**

**ARCOS**

**Controlled Substances Reporting System (CSRS)**

**CSA, CDS, and Other Forms**

**Electronic Prescription for Controlled Substances**

**Inventory of Multiple Prescriptions for Schedule II Controlled Substances**

**License Transfer**

**Manufacture Questions**

**Overdose**

**Overdose Case Management**

**Prescription**

**Registration Procedures**





# DEA Web-Based Resources

[www.DEA.gov](http://www.DEA.gov)

The screenshot shows the DEA website homepage. At the top, the URL bar displays 'http://www.justice.gov/dea/index.html'. The main header features the 'DEA' logo in large yellow letters, followed by 'UNITED STATES Drug Enforcement Administration' and the tagline 'TOUGH WORK, VITAL MISSION'. A navigation bar contains links: HOME, ABOUT, CAREERS, OPERATIONS, DRUG INFO, PREVENTION, and PRESS ROOM. The main content area has a large blue banner with the text 'Tough Work, Vital Mission The Facts About DEA' and a DEA Special Agent badge. To the right of the banner are three boxes: 'Drug Facts for Today's Teens' (JustThinkTwice.com), 'A DEA Resource for Parents' (GetSmartAboutDrugs.com), and 'Wall of Honor' (DEA Remembers). Below the banner are three columns: 'TOP STORY' featuring a headline about a couple's sentences for cocaine trafficking, 'TOPICS OF INTEREST' listing various resources like the DEA Fact Sheet and Marijuana position, and 'RESOURCE CENTER' listing links to the Controlled Substances Act, DEA Museum, and Drug Disposal.

**DEA** UNITED STATES Drug Enforcement Administration  
TOUGH WORK, VITAL MISSION

HOME ABOUT CAREERS OPERATIONS DRUG INFO PREVENTION PRESS ROOM

**Tough Work, Vital Mission**  
The Facts About DEA

**Drug Facts for Today's Teens**  
JustThinkTwice.com

**A DEA Resource for Parents**  
GetSmartAboutDrugs.com

**Wall of Honor**  
DEA Remembers

**TOP STORY**

**Couple Handed Lengthy Sentences in International Cocaine Trafficking Conspiracy**

JAN 29 (BROWNSVILLE, TEXAS)

Norma Alicia Gallegos, 30, and her husband Jose Carlos...

**TOPICS OF INTEREST**

DEA Fact Sheet  
Drugs of Abuse: A DEA Resource Guide  
Extension of Temporary Placement of Five Synthetic Cannabinoids  
The DEA Position on Marijuana

**RESOURCE CENTER**

Controlled Substances Act  
DEA Museum and Visitors Center  
Doing Business with DEA  
Drug Disposal  
Employee Assistance Program





# DEA Web-Based Resources

[www.JustThinkTwice.com](http://www.JustThinkTwice.com)

The screenshot shows the homepage of the Just Think Twice website. The browser address bar displays "http://www.justthinktwice.com/". The website has a dark blue header with the DEA seal on the left and the title "JUST THINK TWICE" in large, bold, yellow and white letters. Below the title is the tagline "YOU'VE HEARD THE FICTION. NOW LEARN THE FACTS." in smaller white text. A navigation bar below the header contains several links: "HOME" (return home), "DRUG FACTS" (learn the truth), "FACTS & FICTION" (know the difference), "CONSEQUENCES" (life changing events), "TEENS TO TEENS" (sharing our experience), and "INSIDE DEA" (find out more). A "SEARCH" button is located on the right side of the navigation bar. The main content area features a large banner for "THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF" with a photo of a young woman. Below the banner is a paragraph explaining that meth is made of toxic chemicals like battery acid, gasoline, and drain cleaner. A link "GET THE FACTS ABOUT METHAMPHETAMINE" is provided. Below this link are three icons representing Marijuana, Cocaine, and Meth. To the right of the banner are two smaller sections: "IT'S TIME TO SNATTER THE MYTHS ABOUT DRUGS AND DRUG ABUSE" with a "Learn More" link, and "FACTS & FICTION" with a "Get the Facts" link. At the bottom, there is a "TEENS TO TEENS" section with a link "Advice from teens on the D.A.R.E. Youth Advisory Board" and a "READ MORE" button. A "Did You Know?" section at the bottom left states: "Combine toxic chemicals with neglected hygiene, and you get a condition called 'meth mouth'—rotten and decaying teeth."

**JUST THINK TWICE**  
YOU'VE HEARD THE FICTION. NOW LEARN THE FACTS.

HOME *return home* | DRUG FACTS *learn the truth* | FACTS & FICTION *know the difference* | CONSEQUENCES *life changing events* | TEENS TO TEENS *sharing our experience* | INSIDE DEA *find out more*

SEARCH

**THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF**

Maybe you've heard it's made of the same stuff as cold medicine. Well, that's not all. Some of the ingredients used to make meth include battery acid, gasoline, and drain cleaner.

[GET THE FACTS ABOUT METHAMPHETAMINE »](#)

MARIJUANA | COCAINE | METH

**IT'S TIME TO SNATTER THE MYTHS ABOUT DRUGS AND DRUG ABUSE**  
[Learn More](#)

**FACTS & FICTION**  
[Get the Facts](#)

**TEENS TO TEENS**  
Advice from teens on the D.A.R.E. Youth Advisory Board  
[READ MORE »](#)

**Did You Know?** Combine toxic chemicals with neglected hygiene, and you get a condition called "meth mouth"—rotten and decaying teeth.





# DEA Web-Based Resources

## www.GetSmartAboutDrugs.com

**GetSmartAboutDrugs**  
A DEA Resource for Parents

Home Identify Prevent Help Hot Topics DEA in the Community Communities of Practice

The new Communities of Practice section includes three PowerPoint presentations about drug abuse and awareness and an online Train the Trainer module that provides presenters with techniques to effectively deliver the presentations

[Learn more](#)

**COMMUNITIES of PRACTICE**

**DEA Publications**  
Download or request  
Drugs of Abuse and  
Prescription for Disaster  
[READ MORE](#)

**Watch the Videos**  
View videos to learn how  
to keep your family safe,  
including ways to avoid  
prescription drug abuse  
[VIEW](#)

**Latest News** [See All News Stories](#)

**Drug Court Offers Hope for the Future**  
Jan 22, 2013 The Columbia River Partnerships for Change, a nonprofit in Oregon, is seeing tremendous success with its three drug court programs: adult treatment, juvenile treatment, and families restored.

**ER Visits Tied to Energy Drinks Double Since 2007**  
Jan 16, 2013 Hospitals around the country have seen a gradual uptick in the number of emergency room visits involving energy drinks.

**Voices**

**Irma Perez's Story**  
Irma was a 14 year old girl from Belmont, California who took an Ecstasy pill on April 23, 2004. She became sick immediately—vomiting and writhing in pain—yet her friends did not seek medical help for her. Instead, they gave her more Ecstasy.

**Inside DEA**  
The men and women of DEA aren't just drug enforcement agents—we're parents, grandparents, brothers and sisters. We've seen how drugs rob young people of their promise and dreams, and how entire families are affected by a child's drug abuse.





***Thank You***